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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: :

MINAKO HIJIKATA ET AL. : GROUP ART UNIT: 1634

SERIAL NO.: 09/813,990 :

FILED: MARCH 22, 2001 : EXAMINER: CHAKRABARTI, A.

FOR: GENETIC POLYMORPHISM OF MXA PROTEIN AND USE THEREOF :

AMENDMENT AND REQUEST FOR RECONSIDERATION

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

Responsive to the Official Action dated July 11, 2002, Applicants respectfully request reconsideration of the above-identified application in view of the following amendments and remarks.

IN THE CLAIMS

Please cancel Claims 1-17.

Please add the following claims.

18. A polynucleotide suitable for predicting the efficacy of interferon therapy using interferon-α and/or interferon-β for treating an individual who suffers from hepatitis C virus, comprising a polynucleotide selected from the group consisting of:

(at) the polynucleotide of Sequence ID No. 1 in the sequence listing;

(bt) a modified polynucleotide derived from (at) by inclusion of one or several

deletions, substitutions or additions at positions except for the 455th position;

(ct) a polynucleotide containing the sequence which spans from the 441st to the 455th position of Sequence ID No. 1;

(dt) a polynucleotide containing the sequence which spans from the 449th to the 459th position of Sequence ID No. 1; and

(et) a complementary strand of the polynucleotide selected from the group consisting of (at), (bt), (ct) and (dt).

19. The polynucleotide of Claim 18, which comprises (at).

20. The polynucleotide of Claim 18, which comprises (bt).

21. The polynucleotide of Claim 18, which comprises (ct).

22. The polynucleotide of Claim 18, which comprises (dt).

23. The polynucleotide of Claim 18, which comprises (et).

24. The polynucleotide of Claim 18, further comprising at least one additional polynucleotide connected to said polynucleotide, the additional polynucleotide being selected from the group consisting of a promoter, an enhancer, an upstream activation sequence, a silencers, a upstream suppression sequence, an attenuator, a poly A tail, a nucleus transport signal, Kozak sequence, ISRE, a drug resistance factor, a gene of signal peptide, a gene of transmembrane domein, a gene of marker protein, a gene of interferon-responding protein, and a gene of interferon-non-responding protein.

25. A polynucleotide suitable for predicting the efficacy of interferon therapy using interferon-α and/or interferon-β for treating an individual who suffers from hepatitis C virus, comprising a polynucleotide selected from the group consisting of:

(ag) the polynucleotide of Sequence ID No. 2 in the sequence listing;

(bg) a modified polynucleotide derived from (ag) by inclusion of one or several

deletions, substitutions or additions at positions except for the 455th position;

(cg) a polynucleotide containing the sequence which spans from the 441st to the 455th position of Sequence ID No. 2;

(dg) a polynucleotide containing the sequence which spans from the 449th to the 459th position of Sequence ID No. 2; and

(eg) a complementary strand of the poly nucleotide selected from the group consisting of (ag), (bg), (cg) and (dg).

26. The polynucleotide of Claim 25, which comprises (ag).

27. The polynucleotide of Claim 25, which comprises (bg).

28. The polynucleotide of Claim 25, which comprises (cg).

29. The polynucleotide of Claim 25, which comprises (dg).

30. The polynucleotide of Claim 25, which comprises (eg).

31. The polynucleotide of Claim 25, further comprising at least one additional polynucleotide connected to said polynucleotide, the additional polynucleotide being selected from the group consisting of a promoter, an enhancer, an upstream activation sequence, a silencers, a upstream suppression sequence, an attenuator, a poly A tail, a nucleus transport signal, Kozak sequence, ISRE, a drug resistance factor, a gene of signal peptide, a gene of transmembrane domein, a gene of marker protein, a gene of interferon-responding protein, and a gene of interferon-non-responding protein.

32. A polynucleotide suitable for predicting the efficacy of interferon therapy using interferon-α and/or interferon-β for treating an individual who suffers from hepatitis C virus, comprising a polynucleotide selected from the group consisting of:

(aa) the polynucleotide of Sequence ID No. 3 in the sequence listing;

(ba) a modified polynucleotide derived from (aa) by inclusion of one or several

deletions, substitutions or additions at positions except for the 455th position;

(ca) a polynucleotide containing the sequence which spans from the 441st to the 455th position of Sequence ID No. 3;

(da) a polynucleotide containing the sequence which spans from the 449th to the 459th position of Sequence ID No. 3; and

(ea) a complementary strand of the polynucleotide selected from the group consisting of (aa), (ba), (ca) and (da).

33. The polynucleotide of Claim 32, which comprises (aa).

34. The polynucleotide of Claim 32, which comprises (ba).

35. The polynucleotide of Claim 32, which comprises (ca).

36. The polynucleotide of Claim 32, which comprises (da).

37. The polynucleotide of Claim 32, which comprises (ea).

38. The polynucleotide of Claim 32, further comprising at least one additional polynucleotide connected to said polynucleotide, the additional polynucleotide being selected from the group consisting of a promoter, an enhancer, an upstream activation sequence, a silencers, a upstream suppression sequence, an attenuator, a poly A tail, a nucleus transport signal, Kozak sequence, ISRE, a drug resistance factor, a gene of signal peptide, a gene of transmembrane domein, a gene of marker protein, a gene of interferon-responding protein, and a gene of interferon-non-responding protein.

39. A polynucleotide suitable for predicting the efficacy of interferon therapy using interferon-α and/or interferon-β for treating an individual who suffers from hepatitis C virus, comprising a polynucleotide selected from the group consisting of:

(ac) the polynucleotide of Sequence ID No. 4 in the sequence listing;

(bc) a modified polynucleotide derived from (ac) by inclusion of one or several

deletions, substitutions or additions at positions except for the 455th position;

(cc) a polynucleotide containing the sequence which spans from the 441st to the 455th position of Sequence ID No. 4;

(dc) a polynucleotide containing the sequence which spans from the 449th to the 459th position of Sequence ID No. 4; and

(ec) a complementary strand of the polynucleotide selected from the group consisting of (ac), (bc), (cc) and (dc) mentioned above.

40. The polynucleotide of Claim 39, which comprises (ac).

41. The polynucleotide of Claim 39, which comprises (bc).

42. The polynucleotide of Claim 39, which comprises (cc).

43. The polynucleotide of Claim 39, which comprises (dc).

44. The polynucleotide of Claim 39, which comprises (ec).

45. The polynucleotide of Claim 39, further comprising at least one additional polynucleotide connected to said polynucleotide, the additional polynucleotide being selected from the group consisting of a promoter, an enhancer, an upstream activation sequence, a silencers, a upstream suppression sequence, an attenuator, a poly A tail, a nucleus transport signal, Kozak sequence, ISRE, a drug resistance factor, a gene of signal peptide, a gene of transmembrane domein, a gene of marker protein, a gene of interferon-responding protein, and a gene of interferon-non-responding protein.

46. A vector comprising the polynucleotide of Claim 18.

47. A vector comprising the polynucleotide of Claim 25.

48. A vector comprising the polynucleotide of Claim 32.

49. A vector comprising the polynucleotide of Claim 39.

50. A method for predicting the efficacy of interferon therapy using interferon-α

and/or interferon-β for treating an individual who suffers from hepatitis C virus, comprising:

1) taking a sample containing a polynucleotide which includes at least one interferon-stimulated response element from the individual; and

2) determining whether the sample contains the polynucleotide of Claim 18, and

3a) predicting that the interferon therapy will be successful for said individual if the sample contains the polynucleotide of Claim 18 or

3b) predicting that the interferon therapy will not be successful for said individual if the sample does not contain the polynucleotide of Claim 18.

51. A method for predicting the efficacy of interferon therapy using interferon-α and/or interferon-β for treating an individual who suffers from hepatitis C virus, comprising:

1) taking a sample containing a polynucleotide which includes at least one interferon-stimulated response element from the individual; and

2) determining whether the sample contains the polynucleotide of Claim 25, and

3a) predicting that the interferon therapy will be successful for said individual if the sample contains the polynucleotide of Claim 25 or

3b) predicting that the interferon therapy will not be successful for said individual if the sample does not contain the polynucleotide of Claim 25.

52. A method for predicting the efficacy of interferon therapy using interferon-α and/or interferon-β for treating an individual who suffers from hepatitis C virus, comprising:

1) taking a sample containing a polynucleotide which includes at least one interferon-stimulated response element from the individual; and

2) determining whether the sample contains the polynucleotide of Claim 32, and

3a) predicting that the interferon therapy will be successful for said individual if the sample contains the polynucleotide of Claim 32 or

3b) predicting that the interferon therapy will not be successful for said individual if the sample does not contain the polynucleotide of Claim 32.

53. A method for predicting the efficacy of interferon therapy using interferon-α and/or interferon-β for treating an individual who suffers from hepatitis C virus, comprising:

1) taking a sample containing a polynucleotide which includes at least one interferon-stimulated response element from the individual; and

2) determining whether the sample contains the polynucleotide of Claim 39, and

3a) predicting that the interferon therapy will be successful for said individual if the sample contains the polynucleotide of Claim 39 or

3b) predicting that the interferon therapy will not be successful for said individual if the sample does not contain the polynucleotide of Claim 39.

54. A method for rendering an interferon-insensitive individual to be interferon-sensitive, which comprises introducing the polynucleotide of Claim 18 into the interferon-insensitive individual.

55. A method for rendering an interferon-insensitive individual to be interferon-sensitive, which comprises introducing the polynucleotide of Claim 25 into the interferon-insensitive individual.

56. A method for rendering an interferon-insensitive individual to be interferon-sensitive, which comprises introducing the polynucleotide of Claim 32 into the interferon-insensitive individual.

57. A method for rendering an interferon-insensitive individual to be interferon-sensitive, which comprises introducing the polynucleotide of Claim 39 into the interferon-insensitive individual.

58. A non-human transgenic animal, into which has been introduced the

polynucleotide of Claim 18.

59. A non-human transgenic animal, into which has been introduced the polynucleotide of Claim 25.

60. A non-human transgenic animal, into which has been introduced the polynucleotide of Claim 32.

61. A non-human transgenic animal, into which has been introduced the polynucleotide of Claim 39.--

SUPPORT FOR THE AMENDMENTS

Original Claims 1-17 have been canceled in favor of Claims 18-61. Newly added Claims 18-61 are supported by the specification at pages 2-43 and by original Claims 1-17. No new matter is believed to have been added to this application by these amendments.

REMARKS

Claims 18-61 are active in this application. Favorable reconsideration is respectfully requested.

The rejection of the claims under 35 U.S.C. §112, second paragraph, are believed to be obviated by the amendments submitted above. The claims have been amended for clarification. Accordingly, withdrawal of this ground of rejection is respectfully requested.

Rejection of the claims under 35 U.S.C. §112, first paragraph, are believed to be obviated by the amendments submitted above. The newly-added claims recite the subject matter indicated as allowable. Withdrawal of this ground of rejection is respectfully requested.

Regarding the Restriction Requirement, Applicants submit that Claims 18-49 are directed to the elected Group. Claims 50-61 are directed to methods (Claims 50-57) or compositions of matter (Claims 58-61) which recite the elected subject matter. Accordingly, Claims 50-61 must be rejoined with the elected claims under the provisions of M.P.E.P. §821.04.

Applicants submit that the present application is in condition for allowance. Early notice to this effect is earnestly solicited.

Respectfully submitted,

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IN THE CLAIMS

--Claims 1-17 (Cancelled).

Claims 18-61 (New).--